REMARKS

Claims 7, 10-12, 28-35, 37-40, 43, 46, 47 and 54-59 are pending in the application with entry of this Amendment. Claims 8 and 44 are canceled without prejudice. Claim 44 is canceled and addresses the objection on page 2 of the Office Action. Claims 7, 28 and 43 are currently amended. The amendments and new claims do not present new matter. Claims 12 and 29 were withdrawn from consideration. It is respectfully requested that these claims be reinstated upon allowance of respective independent claims from which they depend. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicant acknowledges that the following rejections were withdrawn following the Amendment submitted on February 11, 2008:

a. Rejection of claims as allegedly being unpatentable over U.S. Patent No. 4,736,749 to Lundback in view of U.S. Patent No. 6,185,442 to Samson.

b. Rejection of claims as allegedly being unpatentable over U.S. Patent No. 4,736,749 to Lundback in view of U.S. Patent No. 6,185,442 to Samson and further in view of U.S. Patent No. 4,685,466 to Rau.

c. Rejection of claims as allegedly being unpatentable over U.S. Patent No. 4,736,749 to Lundback in view of U.S. Patent No. 6,185,442 to Samson and further in view of U.S. Patent No. 7,020,531 to Colliou.

II. Claims 7, 10, 11, 40, 54 and 57 Are Novel Over Staver

Independent claim 7 and dependent claims 10, 11, 40, 54 and 57 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,469,105 to Staver ("Staver"). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131. Applicant respectfully traverses the rejection and respectfully submits that the rejection is moot.

It is alleged that the insert member 18 described by Staver is a "tube" as recited in claim 7. It is further alleged that the vacuum bell 10 described by Staver is a "suction device" as recited in claim 7.

Initially, Applicant notes that the insert member 18 and vacuum bell 10 components cited in the Office Action are not components of the same device. Rather, the vacuum bell 10 is a

component of a first embodiment of an apparatus described in col. 3, line 41 – col. 4, line 50 with reference to Figs. 1-2 of Staver, and the insert member 18 is a component of a second embodiment of an apparatus described in col. 4, line 51 – col. 6 with reference to Figs. 3-7 of Staver. Staver (col. 3, line 43) ("first embodiment); (col. 4, lines 52-53 ("second preferred embodiment"). Thus, the Office Action relies on components of different devices to allege that claim 7 is anticipated by Staver despite the fact that Staver does not even disclose a device that includes all of the cited components.

Nevertheless, as conceded in the Office Action, Staver fails to disclose, teach or suggest "a flexible tube defining a central axis and having a proximal end and a distal end" and "a suction device formed from a flexible material" as recited in claim 7. Office Action (p. 4). Consistent with this concession is the fact that Staver explains that the "substantially tubular shaped insert member 18 (the alleged "tube") is "formed of a **rigid** material such as metal..." Staver (col. 5, line 10) (emphasis added). It is well understood that a rigid insert member 18 is not a flexible tube as recited in claim 7. Further, the vacuum bell 10 (the alleged "suction device"), which is part of a different apparatus as discussed above, is "fabricated of a substantially **rigid** electrically-conductive material, such as by **injection molding** an electrically conductive plastic ..." Staver (col. 3, lines 53-56 (emphasis added). It is also well understood that such rigid, injection molded components are not, and do not form, a suction device formed from a flexible material as recited in claim 7. In this regard, Staver describes components and material and structural properties thereof that are the opposite of what is recited in claim 7, but the Office Action has not addressed these determinative differences.

Such "flexible" components are also not inherently disclosed by Staver since "rigid" and "flexible" have contradictory meanings. MPEP §2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); MPEP §2163.07 (emphasis added) (To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic

evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP §2112, citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added). *See also, Akami Tech., Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1188 (Fed. Cir. 2003) (A claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present).

In view of the above remarks, Staver also fails to disclose, teach or suggest "the suction device being connected to and coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface" as recited in claim 7. In contrast, as discussed above, Staver describes a substantially rigid vacuum bell made by injection molding.

Moreover, Staver fails to disclose, teach or suggest such a flexible suction device "having a shape and a size for being removably securable to myocardial tissue" as recited in claim 7. Notably, the Office Action has not cited any portion of Staver that actually discloses such a configuration. Instead, Staver explains that the first and second apparatus embodiments are used with an EKG machine, and that the bottom portion of the annular member 13 (Fig. 1, first embodiment) and the bottom portion of the bell 14 (Fig. 3, second embodiment) are applied to the skin of a patient, as would be expected when such devices are used with an EKG machine. In fact, Staver explains that a material 20 that is received within an annular concavity 16 of the vacuum bell 14 is a gel material that facilitate application of the apparatus to a particularly hairy area of skin (e.g., a chest area) by affording a substantially adhesive bond with the skin even in hairy areas. Staver (col. 5, lines 43-59). Thus, Staver is not related to application stimulation electrodes to a myocardial surface, and the Office action allegations are not supported by what is actually disclosed by the cited reference. Further, the Office Action has not established that such devices are inherently configured to be removably securable to myocardial tissue. MPEP §2112; §2163.07 (To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by

probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.)

Staver also fails to disclose, teach or suggest "a tissue stimulation element configured to emit stimulation energy and that is too small to form a transmural lesion in myocardial tissue, the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device" as recited in claim 7. Instead, Staver explains that the two devices are used to hold or receive a mass of electrically-conductive material 13/20 that is part of an electrical path from an EKG electrode terminal. As explained in Appendix 1, and contrary to the Office Action allegations, such devices and electrodes are not used for sending electricity into the body. Attachment 1 (last paragraph).

Since Staver does not expressly disclose such stimulation elements, it must be alleged that it is inherent that the annular members 13/20 are "stimulation electrodes that emit energy" as recited in claim 7. However, the Office Action has provided not extrinsic evidence to establish that such component used with an EKG machine necessarily emit energy, which is understandable in view of Attachment 1 explaining that such machines only record electrical activity of the heart and do not send electricity into the body. MPEP §2112; §2163.07.

Given these deficiencies, it is respectfully submitted that Staver does not anticipate independent claim 7. Dependent claims 10, 11, 40, 54 and 57 incorporate the elements and limitations of independent claim 7 and, therefore, are also believed novel over Staver.

Accordingly, Applicant respectfully requests that the rejection of claims 1, 10, 11, 40, 54 and 57 under §102(b) be withdrawn.

III. Claim 47 Is Patentable Over Staver and Lundback

Dependent claim 47 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Staver in view of Lundback. Dependent claim 47 incorporates the elements and limitations of independent claim 7 and, therefore, is also believed allowable since Lundback does not cure the deficiencies discussed above.

With regard to Lundback, it is alleged that the vacuum tube 8 is a "flexible tube" as recited in Applicant's claims, and that the collection of the electrode plate 1, the sealing component 2, and the back piece 3 form a cup-shaped suction device. Office Action (p. 4). The Office Action, however, fails to address the fact that Lundback explains that the back piece 3 is

substantially rigid. Lundback (Abstract, col. 2, line 27) (emphasis added). The Office Action also fails to address the fact that the substantially rigid back piece 3 and the sealing ring portion 9 of the sealing component 2 work "as an integrated, **rigid unit** ..." Lundback (col. 4, line 64) (emphasis added). Thus, the allegation that the collection of components 1-3 described by Lundback form a flexible suction device made from a flexible material is contrary to what is actually described by Lundback and fails to address the fact that components of the alleged "collection" are rigid and form an integrated, rigid unit.

Staver also teaches away from "a flexible tube defining a central axis and having a proximal end and a distal end" and "a suction device formed from a flexible material ..." a recited in claim 7, from which claim 47 depends. Staver specifically explains that the "substantially tubular shaped insert member 18 (the alleged "tube") is "formed of a **rigid** material such as metal...", and that the vacuum bell 10 (the alleged "suction device"), is "fabricated of a substantially **rigid** electrically-conductive material, such as by **injection molding** an electrically conductive plastic ..." Staver (col. 3, lines 53-56; col. 5, line 10) (emphasis added).

Further, Lundback teaches away from "a flexible tube defining a central axis and having a proximal end and a distal end" and "a suction device formed from a flexible material" as recited in claim 7, from which claim 47 depends, since Lundback describes a collection of components 1-3 that includes a **substantially rigid** back piece 3, and that substantially rigid back piece and the sealing portion 9 of the sealing ring 2 work as an integrated **rigid unit**,

Additionally, given the particular configuration of components for use with ECG/EKG machines, Staver and Lundback both teach away from a suction device formed from a flexible material and having a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue. Instead, the cited references describe devices configured top be applied to a patient's skin, *i.e.*, on the outside of the patient's body. For example, Staver specifically explains that a material 20 that is received within an annular concavity 16 of the vacuum bell 14 is a gel material that facilitate application of the apparatus to a particularly hairy area of skin (e.g., a chest area) by affording a substantially adhesive bond with the skin even in hairy areas. Staver (col. 5, lines 43-59). Similarly, Lundback explains that his device is structured to "give good contact, especially in case of hair growth on the skin." Lundback (col. 3, lines 56-57). Thus, the cited references are not related to application

stimulation electrodes to a myocardial surface and instead are directed to devices that are applied to the skin, particularly a hairy portion of the skin, which is typical in ECG/EKG applications.

Moreover, Staver and Lundback, both of which relate to use of ECG/EKG systems, teach away from "a tissue stimulation element configured to emit stimulation energy" as recited in claim 7, from which claim 47 depends. As discussed above, Appendix 1 explains that components of an ECG/EKG machine are used to record electrical activity of the heart, but do not send electricity into the body. This has not been addressed in the Office Action.

In view of the above remarks, Applicant respectfully submits that Staver and Lundback, individually and even if somehow properly combined, fail to disclose, teach or suggest each limitation of claims 7 and 47, and that the cited references teach away from various elements of these claims.

Accordingly, Applicant respectfully requests that the rejection of claim 47 under 35 U.S.C. §103(a) be withdrawn.

IV. Claims 37 and 38 Are Patentable Over Staver

Dependent claims 37 and 38 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Staver. Dependent claims 37 and 38 incorporate the elements and limitations of independent claim 7 and, therefore, is also believed allowable in view of the deficiencies of Staver discussed above in Sections II and III. Staver is also deficient relative to, and teaches away from, claims 37 and 38.

It is generally alleged, without further support or reasoning, that it is "trivial" to provide the annular conductive member 13 of Staver with the dimensions as recited in claims 37 and 38, i.e., "wherein the tissue stimulation element defines a perimeter of about 1.5 mm to 3 mm" and "wherein the tissue stimulation element defines a thickness of about 0.01 mm."

However, the Office Action fails to consider the fact that the dimensions recited in these claims are on the order of millimeters and fractions thereof, whereas that the device including the member 13 is operable by squeezing (presumably by a physician or medical assistant) a bulb 1 in order to evacuate the bell 10 and ensure contact of the annular member 13 with the patient's skin. Staver (col. 4, lines 23-42) Thus, the dimensions of such devices are of such a larger magnitude that they can be positioned and manipulated (squeezed) by a user. For example, Staver explains that the bell 10 has a diameter of approximately 2.5 centimeters. This fact has not been

addressed in the Office Action, which further fails to consider that smaller dimensions, i.e., an order of magnitude smaller, are not discussed by Staver. Accordingly, the general allegation that such dimensions are "trivial" are not consistent with and are not supported by the structural configuration and manual manipulation of the devices described by Staver.

Further, the Office Action has not established how the conductive member 13 can have a thickness of only about 0.01mm (i.e., a fraction of a millimeter), considering that the conductive member 13 is used with a bell 10 having a diameter and dome height of about 2.5 centimeters, and further considering that the conductive member 13 ensures effective contact with the patient's skin, which may be applied to a hairy part of the patient such as the chest. More particularly, the Office Action has not explained how a structure having a thickness of only about 0.01mm is suitable for attachment to a hairy part of a patient's skin.

Thus, the general, "trivial" allegations, without more, cannot support the rejection since the dimensions recited in claims 37 and 38 are much smaller than the dimensions described in Staver. Consistent with this conclusion is the fact that Lundback, which is also related to devices used with ECG/EKG systems, also describes components having dimensions of 30 millimeters, or 3 centimeters. Lundback (col. 5, lines 20-21).

Accordingly, Applicant respectfully requests that the rejection of claims 37 and 38 under 35 U.S.C. §103(a) be withdrawn.

V. Claims 28, 30, 43, 46, 55, 56, 58 and 59 Are Patentable Over Staver and Lundback

Independent claims 28 and 43 and respective dependent claims 30, 46, 55, 56, 58 and 59 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Staver in view of Lundback. The deficiencies of these references, individually and in combination, relative to various elements of the rejected claims, are discussed in detail above.

Moreover, the cited references fail to disclose, teach or suggest, and are not related to, "a source of stimulation energy" that is operably connected to the tissue stimulation element as recited in claims 28. Both of the cited references are related to devices used with ECG/EKG systems. As explained in Appendix 1, such devices and systems are used to record electrical activity of the heart, but ECG/EKG systems do not send electricity into the body. Therefore, the

cited references are deficient relative to these claims, and also teach away from these claims, as discussed in detail above in sections II and III.

Accordingly, Applicant respectfully requests that the rejection of claims 28, 30, 43, 46, 55, 56, 58 and 59 under 35 U.S.C. §103(a) be withdrawn.

VI. Claims 31-33 and 39 Are Patentable Over Staver and Lundback

Dependent claims 31-33 and 39 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Staver in view of Lundback. Claims 31-33 incorporate the elements and limitations of independent claim 28, and dependent claim 39 incorporates the elements and limitations of independent claim 7 and, therefore, are also believed allowable in view of the deficiencies of the cited references discussed above in Sections II and III. MPEP §2143.03.

Accordingly, Applicant respectfully requests that the rejection of claims 31-33 and 39 under 35 U.S.C. §103(a) be withdrawn.

VII. Claims 34 and 35 Are Patentable Over Lundback, Samson and Colliou

Dependent claims 34 and 35 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lundback in view of Samson and further in view of U.S. Patent No. 7,020,531 to Colliou ("Colliou"). Dependent claims 34 and 35 incorporate the elements and limitations of independent claim 28.

It is conceded that Lundback fails to disclose that the source of stimulation is configured to provide stimulation pulses that are about 1 msec in duration, 10mA and two stimulation pulses per second, and the Office Action cites Colliou for this limited purpose. Colliou, however, does not provide the above-discussed claim limitations missing in Staver and Lundback. Therefore, the cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each element of claims 34 and 35, and certain references teach away from various elements of the claims as discussed above.

Accordingly, Applicant respectfully requests that the rejection of claims 34 and 35 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment and allowance of the application in view of the forgoing remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

VISTA IP LAW GROUP LLP

Dated: July 24, 2008

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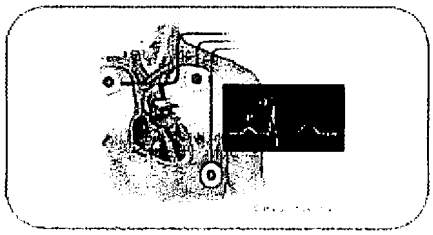
APPENDIX A

http://www.americanheart.org/print_presenter.jhtml;jsessionid=GYS5VLG5SAV1ECQFCXQCDSQ?identifier=3005172

Electrocardiogram (EKG or ECG)



click to enlarge

What is it?
An electrocardiogram — abbreviated as EKG or ECG — is a test that measures the electrical activity of the heartbeat. With each beat, an electrical impulse (or "wave") travels through the heart. This wave causes the muscle to squeeze and pump blood from the heart. A normal heartbeat on ECG will show the timing of the top and lower chambers.

The right and left atria or upper chambers make the first wave called a "P wave" — following a flat line when the electrical impulse goes to the bottom chambers. The right and left bottom chambers or ventricles make the next wave called a "QRS complex." The final wave or "T wave" represents electrical recovery or return to a resting state for the ventricles.

Why is it done?
An ECG gives two major kinds of information. First, by measuring time intervals on the ECG, a doctor can determine how long the electrical wave takes to pass through the heart. Finding out how long a wave takes to travel from one part of the heart to the next shows if the electrical activity is normal or slow, fast or irregular. Second, by measuring the amount of electrical activity passing through the heart muscle, a cardiologist may be able to find out if parts of the heart are too large or are overworked.

Does it hurt?
No. There's no pain or risk associated with having an electrocardiogram. When the ECG stickers are removed, there may be some minor discomfort.

Is it harmful?
No. The machine only records the ECG. It doesn't send electricity into the body.